Conferences and Reviews

Prevention and Treatment of Foot Problems in Diabetes Mellitus
A Comprehensive Program

Discussants
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This discussion was selected from the weekly staff conferences in the Department of Medicine, University of California, San Francisco. Taken from a transcription, it has been edited by Nathan M. Bass, MD, PhD, Associate Professor of Medicine, under the direction of Lloyd H. Smith, Jr, MD, Professor of Medicine and Associate Dean in the School of Medicine.

FLOYD C. RECTOR, MD*: *For patients with diabetes mellitus, a troublesome problem is the development of an infected foot that may lead to the loss of a limb. This is an area of health care in which careful attention to maintenance can make a huge difference. This past year, Laurence Gavin, MD, established a program in our outpatient clinic for the care of diabetic foot problems. For this conference, three specialists in the diabetic foot will discuss this issue. Dr Gavin will outline the magnitude of this problem. There will be subsequent discussions by Richard Stess, DPM, and by Jerry Goldstone, MD.*

Prevalence of Diabetic Foot Problems

LAURENCE A. GAVIN, MD†: We use the term "diabetic foot" to describe the downward spiral of complications that occur in patients with diabetic neuropathy which predisposes them to foot trauma, ulceration, then infection, gangrene, and possibly amputation. In this conference we address the identification of the risk factors that lead to the development of these end-stage foot complications and how to intervene and try to prevent this downward spiral. There is a grim aphorism: "Give diabetes an inch and it will take a foot." A typical case history follows.

Illustrative Case 1

The patient, a 61-year-old man with non–insulin-dependent diabetes mellitus of two years' duration, was admitted to the University of California, San Francisco (UCSF), Medical Center in August 1990 for the management of a right plantar ulcer secondary to burns from a radiator. While in Australia on vacation during the winter, he placed his cold foot on a radiator, fell asleep, and woke up sometime later to the smell of burning flesh. He was transferred from Australia to UCSF for management. His relevant medical history relates to diabetes mellitus that was discovered two years ago in association with an infected left foot and that progressed, resulting in a below-the-knee amputation. Additional complications at that time included proliferative diabetic retinopathy, later treated with laser, and substantial foot neuropathy. He smoked cigarettes. His treatment consisted of diet plus an oral hypoglycemic agent.

Examination at the time of admission showed the retinopathy, left below-the-knee amputation, and an ulcer on the plantar aspect of the right foot. He had normal foot pulses and pressures. We advised more comprehensive care of his diabetes and referral to the High Risk Diabetic Foot Program.

Discussion

Patients with diabetes mellitus are at a much higher risk of gangrene (15-fold) compared with persons without diabetes. Of all our diabetic patients, 20% are admitted to the hospital annually for the care of their feet and associated problems. Half of all nontraumatic major limb amputations are in this patient population. This results in about 35,000 amputations annually in the United States. The amputation rate is 1% overall and 10% for diabetic patients older than 65 years. The dollar cost of this problem is approaching three quarters of a billion dollars per year.[1,2]

Peripheral neuropathy—a diffuse symmetric neuropathy of stocking distribution—is the dominant problem or lesion predisposing to these problems. Pure neuropathy is present in 60% of patients with foot ulcers, pure ischemia in 20%, and combined neuropathy with peripheral vascular disease in the other 20%. Neuropathy with or without peripheral vascular disease is present in as many as 40% of patients with non–insulin-dependent diabetes (type II) after 20 years and is somewhat less prevalent (20%) in those with insulin-dependent diabetes (type I). About 30% of neuropathic patients have insensate feet and are unaware of the neuropathy. After the initial amputation, the problem is progression with future lower extremity amputation in many cases. This occurs in 30% of patients within three years and 50% after five years. Mortality is even more staggering: 50% of patients die within five years after their first major foot or leg amputation. The major causes of death are stroke, heart attack, and complications associated with the diabetic foot.[3-5]

Prevention is the key principle of management. Studies in

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ABBREVIATIONS USED IN TEXT

UCSF = University of California, San Francisco
VA = Veterans Affairs

the United States and Europe have shown that preventing half of these amputations is feasible.[6,7] First we need to recognize and reduce the risk factors associated with this downward spiral of complications. Foot care must be optimized and programs of foot care education established. Studies at established centers for the care of patients with diabetic foot problems have demonstrated the success of integrated, multispecialty care programs. Timely intervention can prevent many of these problems and lead to a dramatic improvement in the quality of life of diabetic patients. This also results in major savings in health care costs.

Defining Risk for Foot Problems

A recent study done by Holewski and others at the Department of Veterans Affairs (VA) Medical Center in San Francisco compared a series of diabetic patients without a history of foot ulceration or amputation with a group of diabetic patients with a history of ulceration or amputation.[8] The aim was to define the risk factors associated with progression. Of 90 patients who were studied, 13 had a history of ulceration and amputation; the rest had no end-stage problems.

Retinopathy was much more prevalent in the group who progressed to amputation or had a history of ulceration. Retinopathy indicates microvascular disease, so it is indirect evidence of microvascular disease in the foot. The group with complications also had abnormal ankle-brachial indexes. This test compares the blood pressure at the ankle with pressure in the brachial artery. A ratio of less than 0.6 indicates serious peripheral vascular disease. Although vasculopathy is an important component, it is not the dominant factor predisposing these patients to foot complications.

Somewhat surprising, bunion deformity and callus formation were not different between the groups. Patients with diabetic foot problems do tend to have an increased incidence of callus associated with abnormal biomechanical pressures, but in this study the difference between the groups was not significant.

The most important differences between the groups related to features associated with neuropathy. Dorsiflexion at the ankle was greatly impaired in the patients with complications as opposed to those without complications. The prevalence of foot deformity, such as hammertoe, showed a dramatic difference. Autonomic neuropathy as determined by EI ratios—the ratio of the mean of the longest RR interval during expiration to the mean of the shortest RR interval during inspiration during deep breathing (6 breaths per minute) and electrocardiographic monitoring—was also significant in those with complications compared with the control group. Finally, peripheral neuropathy as determined by abnormal cutaneous pressure sensations was more prevalent in the group with complications. Ankle reflexes, surprisingly, were not different between the two groups. Thus, this study provides us with a list of significant differences that should indicate high-risk components that predispose to the development of foot trauma, ulceration, and possibly amputation.

It is important to note that these risk factors were present in both groups; it was not an all-or-nothing phenomenon. Despite this possible shortcoming, we have applied these findings as well as risk factors defined in other studies to develop an approach to risk stratification. A weighted risk scale was developed (Table 1) that allows us to stratify patients in low-, medium-, or high-risk groups. The patient in the case presented here would fall into the medium-risk category. He had had previous amputations (weighted value 3), treated retinopathy (1), smoked (1), and had neuropathy (3). These risks add up to a score of 8 on the weighted scale. Vasculopathy is given a low weight on this scale, and, in fact, patients with peripheral vascular disease in the absence of neuropathy, while they are at risk, do not have the high-risk components that we classically see in patients with the neuropathy. The dominant predisposing role of neuropathy and its associated changes such as deformity and gait changes are well documented. Note that patients with Hansen's disease have the same type of peripheral neuropathy as patients with diabetes but have normal circulation; yet, almost identical complications develop. The weighted risk scale has allowed useful comparative studies that have identified the important effects of neuropathy. When used to stratify patients and categorize the levels of risk, this approach facilitates the development of a management plan aimed at the prevention of complications. Thus we can intervene and objectively assess whether or not the intervention is beneficial.

TABLE 1.—*Diabetic Foot Risk Factors for Progression to Ulceration*

Risk Factor	*Weighted Value**
Vasculopathy	1
Structural deformity	2
Loss of protective sensation	3
Heart disease or smoking history	1
No. of years with diabetes (>10)	2
Nephropathy or retinopathy	1
Previous ulceration or amputation	3

*Low risk, 1 to 3; medium risk, 4 to 8; high risk, 9 to 13.

Evaluating Diabetic Neuropathy of the Foot

Neuropathy in diabetic patients is classically of the stocking-and-glove type—peripheral, diffuse, and symmetric. Affected patients have pain, paresthesias, or numbness. Pain, which can be excruciating and a challenge to alleviate, afflicts only a small percentage of diabetic patients who have neuropathy. Most have a history of paresthesia and numbness or, more important, insensate feet. A number of studies, including the VA Medical Center report,[8] emphasize that, in fact, a third of the patients have insensate feet. These patients are typically unaware of this loss of sensation and consequently traumatize their feet, inflict injury, and develop ulcerations, infection, and gangrene that ultimately lead to amputation. The important point is that physicians need to both take a careful history and examine the feet. Careful objective testing must be done to detect and quantify the degree of neuropathy.

Another point is that a diabetic foot with neuropathy is warm, with bounding pulses, and may appear clinically fairly healthy. That foot is at high risk, however. In contrast, a foot with peripheral vascular disease is usually cold, with intact but atrophic shiny skin, absent pulses, and associated with a history of intermittent claudication and night pain.

Although that foot is also at risk, it is not at as high a risk as a neuropathic foot. Thus, the detection of neuropathy should lead to an intense foot-care education program and the development of a comprehensive care plan. A standard examination can detect neuropathy, but does not quantitate the severity. Neuropathy cannot be quantified by pinprick, light touch, or a vibrating tuning fork. It is, however, feasible to quantify neuropathy using Semmes-Weinstein probes. These monofilament nylon fiber probes are attached to a plastic handle. They are carefully engineered and have been used for the past 30 years. They are graded in size so that pressure perception thresholds can be reproducibly determined.[9,10]

The probe is applied to the plantar aspect of the foot. A specific amount of force (pressure) is used to bend the monofilament, and the patient is requested to report sensation. The method used is not just a simple matter of touching; it is called an alternative forced-choice method, and patients are asked whether they did or did not feel the probe. In this way a response bias tends to be obliterated. Testing is performed at six sites on the base of the foot over the metatarsal heads. Requiring detection in at least three of these sites results in a high sensitivity and specificity (>90%).

Using this simple office test, it is feasible to quantify the degree of sensory neuropathy. The sensory perception threshold can be determined, and from this and other associated risk factors, the level of risk for complications can also be determined.

The validity of the data generated by the Semmes-Weinstein probes has been documented by another recent study by Holewski and the San Francisco VA Medical Center group. They studied the following groups: a control group (nondiabetic), a diabetic group without neuropathy, a diabetic group with neuropathy but without complications, and a diabetic group with neuropathy and foot ulceration.[9] Three sites on the plantar aspect of the forefoot were tested to determine the absence of sensation or the degree of sensation reduction. The first two groups (control group without diabetes, and patients with diabetes without neuropathy) had normal sensation. The third group, diabetic patients with neuropathy but without ulceration, had a sensory threshold deficit at the level of 5.07—they could feel this probe size but not smaller probes. The group with ulceration and neuropathy had pronounced impairment of sensation. Their threshold was 6.1, a level indicative of an insensate foot. Using these probes, Holewski and associates were able to differentiate patients without ulcer from those with ulcer in the setting of neuropathy.[9] The 5.07 probe level is now considered to be the sensory protective threshold; patients who have an inability to feel at this probe level are at high risk for progression to foot trauma, ulceration, and gangrene. This study and others have confirmed that the Semmes-Weinstein probes can be used to identify and stratify patients with neuropathy according to the degree of risk.

The development of foot deformity is frequently associated with neuropathy, and this progression places patients in a higher risk category. In diabetic patients with neuropathy, decreased foot fat pads, edematous feet, bunions, callus, hammertoe, and occasionally deformity from Charcot bone-joint degeneration develop. The classic hammertoe deformity in patients with diabetic neuropathy can produce abnormal pressures over the metatarsal heads. These patients have flexion of their toes at the metatarsophalangeal joints and get a cocked-toe deformity. They are at high risk for ulceration on the tops of the toes and, more important, on the ball of the foot. As this deformity develops, the fat-pad protective layer is reduced, the heads of the metatarsals are exposed, and ulceration occurs over the heads. This type of deformity is associated with a notable alteration in the pressure distribution on the sole of the foot and predisposes to these further complications.

After foot abnormalities are detected, I refer patients for further studies to evaluate the extent of foot pressure changes or for vascular analysis. Dr Stess discusses the analysis of foot pressures in the diabetic foot.

Analyzing Foot Pressures

RICHARD M. STESS, DPM*: Our interest in the treatment of diabetic foot problems has evolved and developed over the past five years. Components of the work were originally initiated at the Hansen's Disease Center in Carville, Louisiana. The work of our group at the VA Medical Center in San Francisco was first planned to identify objectively those problems to which Dr Gavin has alluded. We have applied the expertise of Paul Brand, MD, of the Carville center, who noted that repeated high pressure or continuous lower pressures over a period of time will cause localized tissue ischemia. It was not feasible to evaluate the plantar components of foot pressure quantitatively until a new instrument developed in Munich became available in the United States.[11] The VA Medical Center in San Francisco was one of the first centers to obtain the EMED Dynamic Gait System, and there is now one at UCSF.[12] The system involves a sensor platform onto which the patient walks with a normal stride and cadence. The sensor platform is built into a walkway about 6 m (20 ft) long. We attempt to have the patient's foot strike the platform on the third or fourth footstep. The sensor platform, or force plate, contains about 2,000 capacitive transducers, with 2 sensors per cm^2. The maximum force that can be measured is 10,000 newtons, with each sensor achieving a maximum of 127 N. There are several other similar types of pressure analysis instruments available, including the pedobarograph developed by Boulton in England.[13,14] The unique capacitive transducer design of the EMED system, however, allows this unit to produce values that are accurate and reproducible to within 5%. Once the pressures have been obtained, computer analysis allows both a graphic interpretation and statistical analysis of an individual footstep or a grouping of steps. Further, particular zones on the foot can be isolated and then studied for more finite values and a comprehensive evaluation.

Figure 1 shows a computerized summation of pressures (mountain peaks) detected by each sensor throughout the gait cycle. The peaks of pressure visualized can be related to the reference line (87 N per cm^2) to appreciate the relative peaks and troughs of pressure achieved through a normal footstep. A normal gait cycle can be viewed in sequence—heel contact, midstance, and toe-off. The heel-contact phase is illustrated on the right side of the figure. As the footstep progresses to midstance or a flat-foot position, there is a transfer of forces. There is a fairly even distribution of pressure between the heel and the forefoot. As weight is transferred, there is a beginning of higher pressure underneath the second metatarsal. As the heel lifts off the ground, there is a dramatic spiking of pressure (left side of figure) that is far greater than

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the reference line. This is considered the propulsive phase of gait. In a recent study, we determined that most neuropathic diabetic ulcers developed under the ball of the foot during this phase.[13]

In addition to the mountain peak graph, the EMED software allows us to view each footstep in a multihued graph with corresponding graphs for peak pressure, force, and area (Figure 2). Pressures are assigned colors from white (low scale) to magenta (high scale) (here shown as black), which are displayed on the color monitor. Forces greater than 30 N per cm^2 are assigned the magenta color and can be seen easily. The gait line, or the center-of-force line, is the line that the computer calculates and displays on the footprint. The force line visualized in the center graph is biphasic, with the peaks representing heel contact and toe-off. The lower right graph represents the surface area of foot contact with the force plate. The computer allows the identification of specific zones of the foot or times. In essence, to study the function of the foot and determine the normal or abnormal pressure and force patterns, each footstep can be reproduced an indefinite number of times. This is valuable in determining which methods, medical or surgical, might be used in the treatment of a recurrent pathologic foot condition such as a plantar hyperkeratotic lesion or hammertoe deformity.

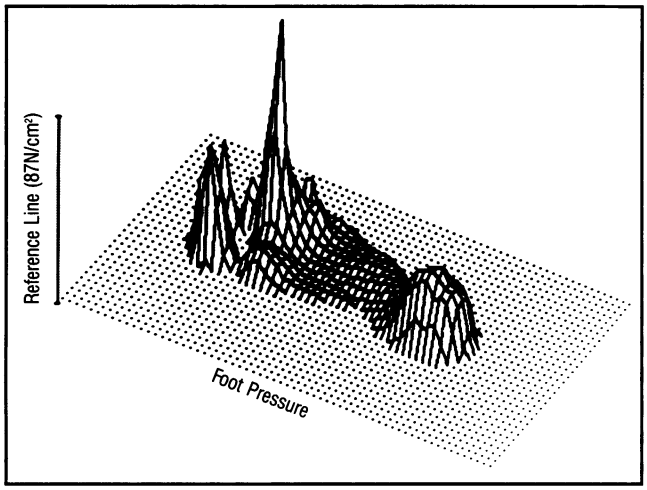

Figure 1.—The summation pressure graph is generated by the EMED Dynamic Gait System during a normal gait cycle. The reference line (left side) represents pressure at 87 newtons (N) per cm^2. The mountain peaks on the sensor grid (2 sensors per cm^2) represent the normal pressure pattern generated (from right to left) by heel contact, midstance, and toe-off during walking.

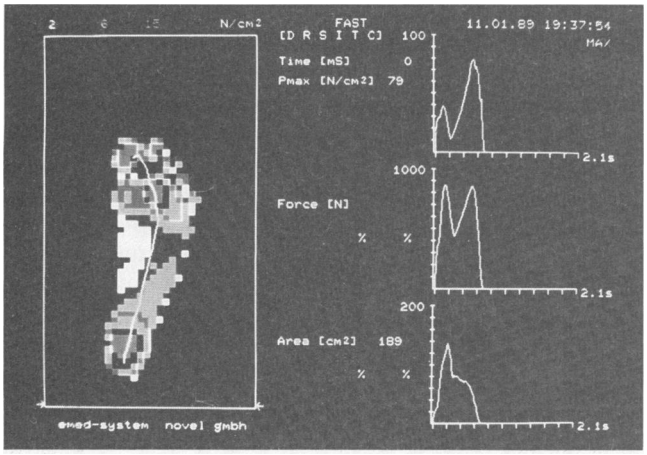

Figure 2.—The EMED measurement shows the pressure distribution during gait as a conformed color picture (left)—given here in black, white, and shades of gray—and as linear graphs (right). The numbers above the picture indicate the various pressure ranges. The linear graphs show the temporal relationship (time horizontal) between pressure (Pmax), force (in newtons), and area (cm^2) at the point of maximum pressure (vertical axis).

Illustrative Case 2

The following case history illustrates the usefulness of the EMED study. The patient, a 68-year-old man with type II diabetes, presented with a Charcot foot deformity. We had been unsuccessful for more than six months in managing a large plantar ulceration despite weekly visits with aggressive debridement of peripheral callous tissue and the provision of custom orthotic devices and molded shoes (Figure 3). An

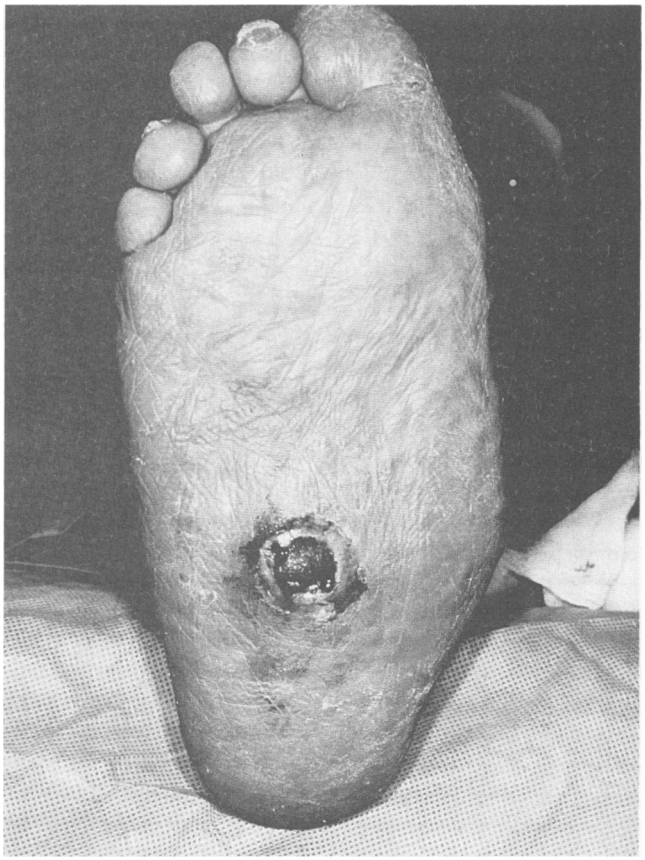

Figure 3.—A neuropathic midplantar foot ulcer is shown in a 68-year-old man with type II diabetes mellitus and a Charcot foot deformity.

EMED study revealed an abnormally high pressure zone located at the midtarsal joint corresponding to the ulcer site (Figure 4). This pressue continued at this magnitude through the entire gait cycle, indicating that these high pressures were applied to this area of the foot through the entire contact phase of the gait. The pattern, both on the color printout and the mountain peak, differed from the normal pattern shown in Figure 2. An x-ray film of the patient's lateral foot showed substantial deformity throughout the midtarsal region corresponding to the point of persistent ulceration (Figure 5).

Because of the extent of the deformity and continuous pressures over the cuboid, it was thought unlikely that we could successfully manage this patient in a conservative manner. The patient underwent surgical foot reconstruction in which the plantar prominence of the cuboid and the surrounding osseous structures were resected and slightly sau-

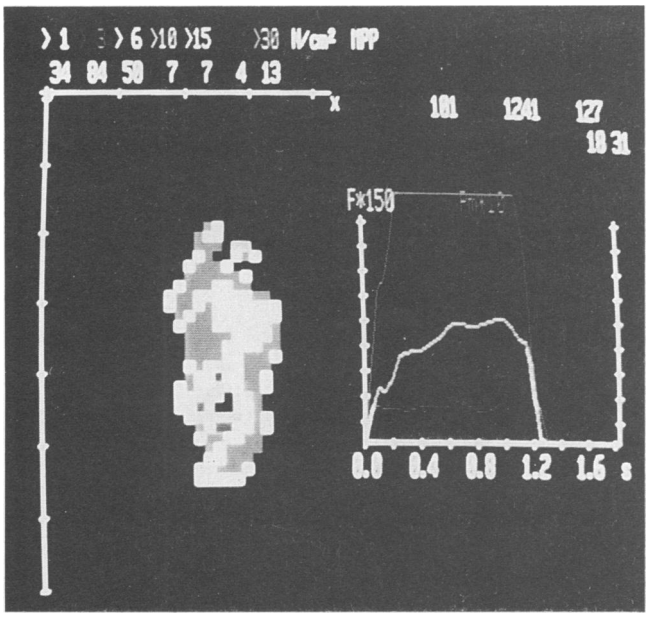

Figure 4.—An EMED study of the foot shown in Figure 3 reveals a high pressure area located to the midtarsal joint (left). The pattern and the graphic pressure printout (right) are grossly abnormal because of the Charcot deformity (compared with the normal pattern in Figure 2). The biphasic pattern is absent, and the peak pressure is 127 N per cm².

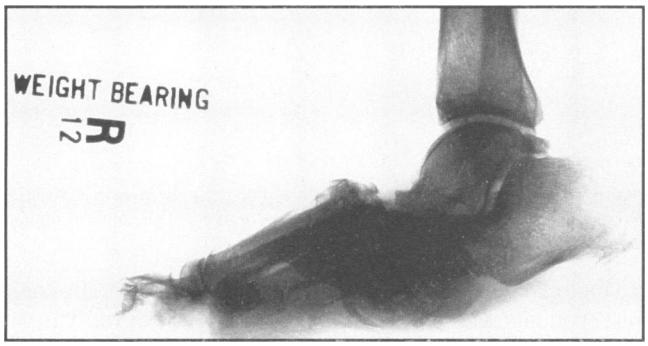

Figure 5.—A lateral x-ray film of the Charcot foot deformity shown in Figure 3 reveals substantial deformity in the midtarsal region. The cuboid bone is subluxed and prominent, and the talus is notably plantar depressed and subluxed.

cerized. The postoperative EMED study is shown in Figure 6. The general pattern is not much different from that of the preoperative study, but the peak pressures are now only 61 N per cm² compared with the earlier preoperative study. Although the pattern was the same, the lowered peak pressures resulting from the resection of bone evolved into a lowering of the pressure-time integral. To evaluate the success of the operation, we took individual sensors (Figure 7) similar to those that are built into the force plate and placed them directly on the patient's foot, which was then placed in his shoe. Thus we were able to determine the extent to which pressures were reduced in normal shoe walking.

The EMED system is indispensable in several areas, including in assessing preoperatively and postoperatively corrective foot operations in diabetic patients, in evaluating the effect of insole materials in attenuating peak pressures and forces, and in analyzing the effects of walking and running on the biomechanics of the foot in various types of shoes and barefoot. The EMED system will undoubtedly add to our knowledge and enhance our ability to treat diabetic patients who have neuropathic foot disorders.

Vascular Disease in the Diabetic Foot

JERRY GOLDSTONE, MD*: As pointed out earlier by Dr Gavin, there is a high incidence of lower extremity amputations in diabetic patients, and once a patient with diabetes has undergone a lower extremity amputation, there is a high likelihood of a second amputation being required within three to five years.

Vascular disease is evaluated in functional segments in the lower extremities: aortoiliac, femoropopliteal, and then infrapopliteal or tibioperoneal. One of the characteristics of

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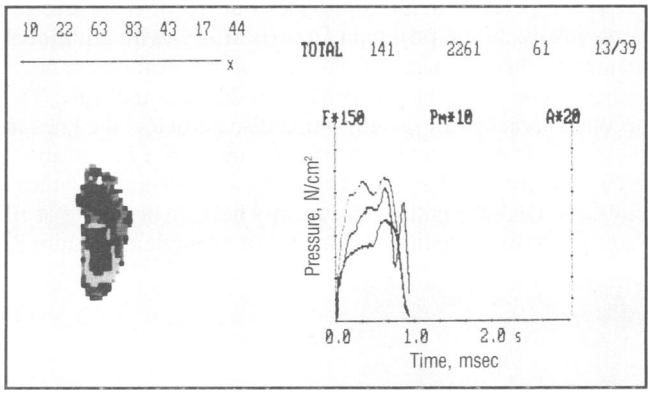

Figure 6.—An EMED study done postoperatively on the Charcot foot deformity (Figures 3 to 5) shows a significant reduction in peak pressure to 61 N per cm², which facilitated healing. F = force, Pm = maximum pressure, A = area

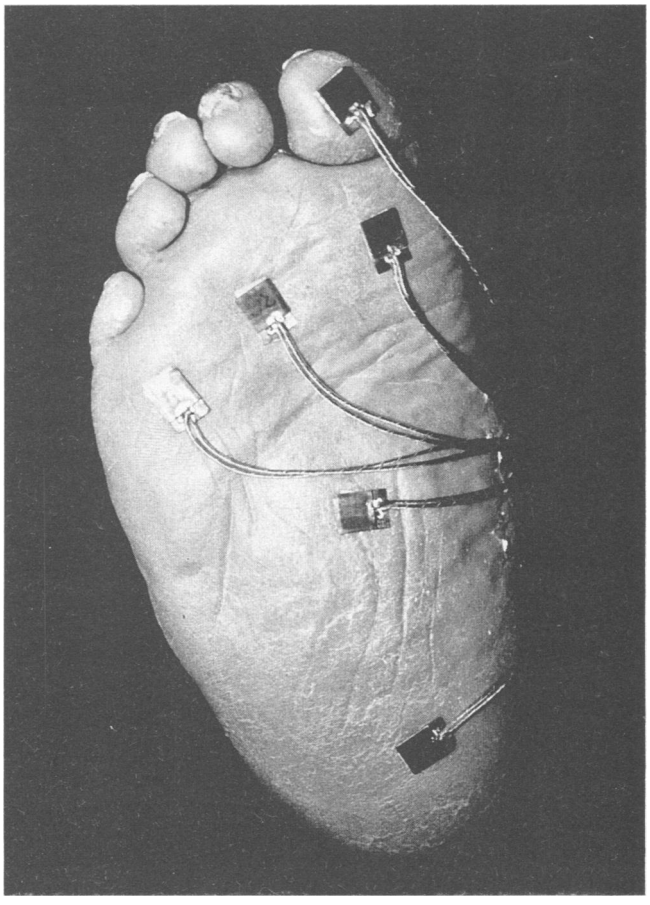

Figure 7.—Individual foot sensors are used to determine foot pressure distribution in the shoe during walking.

diabetic vascular disease is that its distribution is different from that in persons without diabetes. Aortoiliac disease occurs in about 13% of diabetic patients versus 25% of patients without diabetes—that is, diabetic persons tend not to have proximal or aortoiliac disease nearly as frequently as nondiabetic persons do. On the other hand, the profunda femoris (deep femoral) artery tends to be more seriously involved, in both severity and degree, in patients with diabetes than in those without. Lower limb amputations in nondiabetic persons with vascular disease have a typical pattern of superficial femoral artery occlusion with a widely patent deep femoral artery supplying collaterals to the leg. In contrast, diabetic patients typically have widely patent common femoral and superficial femoral arteries but major occlusive lesions involving the profunda femoris artery, with additional lesions further downstream. Disease of the profunda femoris artery is one of the characteristics of diabetes mellitus. The second characteristic is substantial disease below the knee in the tibial arteries, with the relative incidence being about 90% of diabetic persons versus only 10% of those without diabetes. Diabetic patients frequently have involvement of all three of the infrapopliteal arteries. For example, in Figure 8,

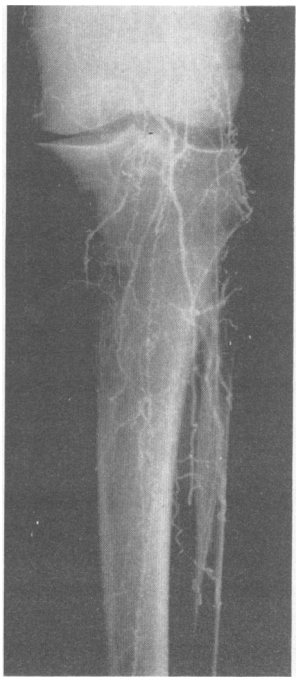

Figure 8.—An arteriogram taken below the knee shows the vascular pattern in a diabetic patient. Note the absence of major vessels with collateral formation.

note the lack of any major vessel between the knee and where collaterals begin filling in the midcalf. The recognition of these disease patterns has led to advances in surgical treatment.

Clinical Evaluation of Vascular Disease

The clinical evaluation of the distribution of vascular disease is most important in diabetic patients, and Doppler pressure measurements are of much value. The arteriogram is used only as part of the preoperative evaluation. Diabetic persons also display different patterns of gangrene. Figure 9 shows an infected foot in a diabetic patient. As Dr Gavin indicated, these patients may have normal pulses and normal circulation but are suffering primarily from an infectious process. This is not so much an ischemic problem, at least of the macrovascular type, but is due to neuropathy and microangiopathy, probably complicated by infection. In contrast, patients with focal gangrene of the toes generally have severe macrovascular disease. Figure 10 shows the foot of a patient who had poor foot circulation with absent pulses and occlusion of the major axial arteries.

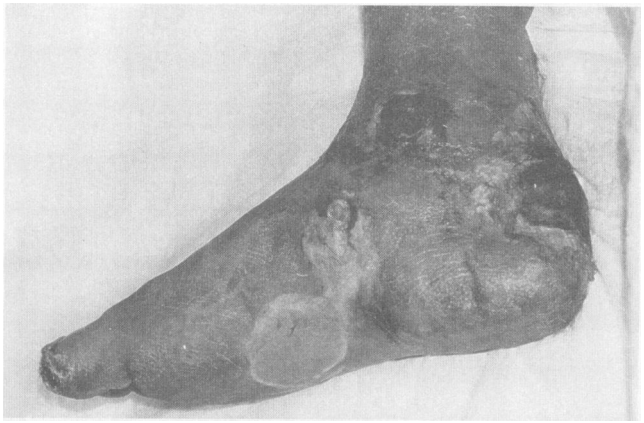

Figure 9.—Neuropathic ulceration and infection are shown in the foot of a patient with diabetes. There is diffuse involvement due to multiple pressure sites.

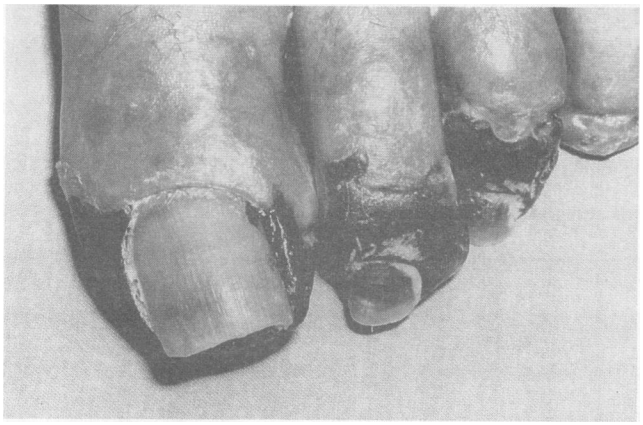

Figure 10.—Gangrenous toes occurred in a diabetic patient with extensive macrovascular disease. Ischemic changes are confined to the area of digital vascular distribution.

Clinically, we can obtain some objective evidence regarding the nature of the vascular disease. The simplest approach and the one used most commonly is an evaluation of the ankle-brachial index. This index is the ratio of the systolic blood pressure in the ankle to that in the arm. Normal persons have an index of greater than 1; the blood pressure in the ankle is slightly greater than it is in the arm. Patients who have intermittent claudication tend to have ratios in the range of 0.6 to 0.8. Those who have severe vascular disease, with resting pain or impending gangrene, have levels in the range of 0.1 to 0.3. This gives some quantifiable and reproducible estimate of perfusion of the lower extremities and can be correlated with some of the physical findings.[14,15] In a recent study of patients who had bypass grafts for lower extremity ischemia, the average ankle-brachial index before surgical treatment was only 0.32. This ratio is thus typical for patients with severe disease who often will require distal vascular surgical reconstruction.

Sometimes in a diabetic patient, an "arteriogram" may occur without any contrast medium (Figure 11). Note the outline of the tibioperoneal trunk. The arteries are heavily calcified, and this creates a problem in determining ankle

pressures. The presence of calcification makes the ankle-brachial indexes, or the ankle pressures themselves, unreliable in many diabetic patients. Calcification of vessels leads to an artificially high pressure measurement, and physicians must be careful in evaluating and interpreting the results of simple tests like the ankle-brachial index in diabetic patients.[16] A useful strategy in a diabetic patient who has these "stiff" arteries is to measure toe pressures.[17] Plethysmographic cuffs are available that can be placed around the toes, and an absolute toe pressure can be measured rather than a ratio. When the toe pressure falls below 30 mm of mercury, the likelihood of foot lesions healing goes down dramatically,

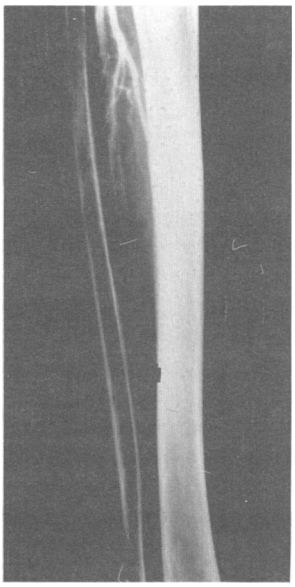

Figure 11.—An x-ray film of the leg in a diabetic patient shows advanced arterial calcification.

and, in virtually every category, diabetic patients heal less well than do nondiabetic patients. The ankle-brachial indexes are useful, but if they are normal, it is good practice to measure toe pressures and analyze the waveforms.

Figure 12 shows a diagram of the arterial ultrasonographic waveform. This is a normal femoral artery tracing with a substantial reversed component in diastole. The waveform is a more sensitive index of the degree of arterial insufficiency in a diabetic patient than is the absolute pressure measurement or the ankle-brachial index.[16] Thus, it is possible to detect and quantify vascular disease in diabetic patients with ankle-brachial indexes, with toe pressures, and by examining the ultrasonographic waveforms. These are all simple tests that can be done at the bedside, in a vascular laboratory, and in a diabetic foot clinic.

Vascular surgeons are often asked to see patients who need debridement, amputation, or both. Sympathectomy is seldom used anymore and can be dismissed from consideration in these patients. Arterial reconstruction is often required, with efforts being directed toward salvaging either the foot or, more important, the knee. The techniques that are used are either surgery or less interventional methods. Two new approaches are balloon angioplasty, which seems to work well for local lesions, and laser-assisted angioplasty, which has had tremendous media coverage but unfortunately has not met with much success in patients. In fact, we have abandoned our laser program because it was generally unsuccessful.

Finally, the development of new microvascular instruments, such as intraluminal vein valve cutters and microvascular scissors for cutting valves, has increased the interest in doing bypass operations more distally—that is, onto the foot—than was previously feasible. These instruments have all been developed for use in the so-called in situ saphenous vein technique.[18] For example, it is now possible to extend these bypass operations to the dorsum of the foot using the saphenous vein, and this results in a high rate of limb salvage. Even in diabetic patients the results are good because even among those who have disease at this level, almost every patient has at least one adequate artery in the foot. There are now cases in which it is possible to salvage feet even in a diabetic patient with advanced vascular disease. The keys are an early recognition of the problem and aggressive management of all foot lesions.[19] Through a comprehensive approach, we should be able to save more extremities.

Conclusion

DR GAVIN: I would like to complete this discussion by emphasizing some key points in our approach to the management of the diabetic foot. First, we try to identify patients with high-risk factors for foot trauma. Next, we stratify the patients according to risk and objectively quantify the degree of risk for each individual foot. We must recognize the presence of risks and problems in association with both neuropathy, which is the dominant deficit, and peripheral vascular

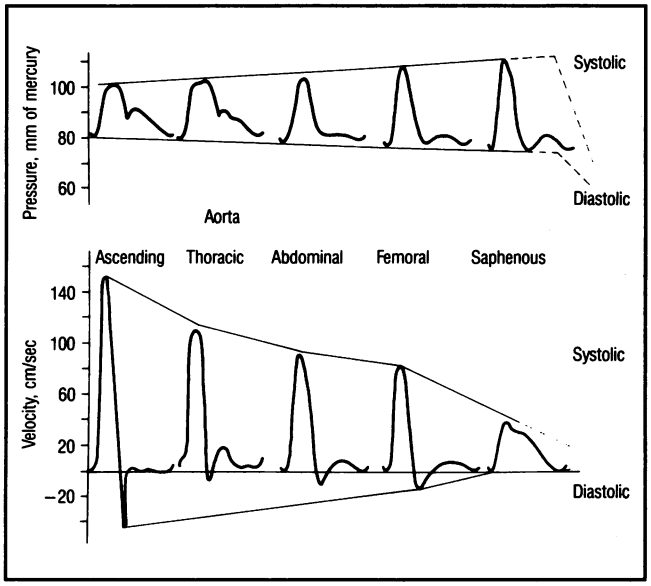

Figure 12.—Doppler ultrasonographic waveform analysis of leg circulation is shown in a normal subject. The normal arterial waveform is triphasic: systolic component (positive), diastolic component (negative), and a low positive rebound. The waveform pattern and amplitude changes are analyzed in the interpretation of ultrasound studies.

disease. Second, once a high-risk state is identified, patients are referred to the appropriate subspecialist, such as a vascular or orthopedic surgeon, for further management. Early intervention for the correction of a foot deformity or timely vascular bypass is critical for foot salvage.

Finally, the interdisciplinary approach is important, as is the availability of a combined care team for the management of diabetic foot problems. One of the first such combined programs was set up at the Joslin Clinic (Harvard University, Boston, Massachusetts), and there are now several excellent centers in the United States and in England. The main reason

for the success of these programs is patient education. All patients must be repeatedly instructed in the dos and don'ts of foot care; handouts are extremely important. A critical aspect of management that is frequently overlooked is that many of these foot problems develop because of poorly fitting shoes. Appropriate shoe prescription and referral to an orthotist for orthotic or custom shoes are important. In addition, patients need close follow-up to determine that the shoes are correct and to reeducate and remotivate them so that they in fact wear the shoes. In the past, these shoes were typically unattractive, and patients refused to wear them. There is no point in having good shoes if patients do not wear them. There now is a fine range of custom shoes available.

Thus, with a well-coordinated foot program, effective intervention is possible. The amputation rate can be reduced by 50%, resulting in a better quality of life for diabetic patients and a considerable saving in health care costs.

Questions and Answers

PHYSICIAN IN THE AUDIENCE: *Are all of the diabetics who come to the clinic evaluated with respect to their neuropathy? Are they tested with Semmes-Weinstein probes, and also do they all get an ankle-brachial index analysis?*

DR GAVIN: Yes, all of our diabetic patients are evaluated with the Semmes-Weinstein probes. This is our approach to quantify neuropathy. We also do the other standard clinical tests to check for neuropathy. We subsequently stratify them and place them into the various risk categories. We do an ankle-brachial index in all cases. We have our own Doppler system, so we can measure both the arterial pressures and, as Dr Goldstone pointed out, review the waveform. Depending on the results of those two basic office procedures, we then refer the patient for further studies. If we find abnormal sensation, we refer the patient, especially those with foot deformity, for the EMED pressure study; if the results of the Doppler study are abnormal, we refer to a vascular surgeon for further analysis.

PHYSICIAN IN THE AUDIENCE: *How often do you repeat these tests?*

DR GAVIN: We apply criteria similar to those for the follow-up of retinopathy and nephropathy. We test with the probes on an annual basis for patients at low risk. In a high-risk patient, we check more frequently. Each visit also entails education, the reselection of footwear, foot care, and remotivation. We tell all of our patients, "Wherever you go for health care, always take off your shoes when you enter the doctor's office." Physicians tend not to examine feet. Only 12% of physicians in studies across the country take the time to examine the feet of a diabetic patient. This percentage is considerably higher (80%) in clinics with dedicated diabetes care programs, but even there, foot examination is something that gets overlooked. Patients come in with congestive heart failure and other problems associated with diabetes; these take priority. The feet tend to be neglected.

PHYSICIAN IN THE AUDIENCE: *How is the duration of diabetes weighted as a risk factor?*

DR GAVIN: The duration of diabetes is a risk factor. The patient in the first illustrative case had diabetes diagnosed clinically only two years ago. However, we know that patients with type II diabetes have a long preclinical phase during which complications develop. This patient clearly had advanced diabetic retinopathy and neuropathy. A duration of longer than ten years is considered a risk factor.

PHYSICIAN IN THE AUDIENCE: *It is frequently said that a nondiabetic nonsmoker will not get an amputation for ischemia. My question for Dr Goldstone is, how often do you see ischemic disease requiring amputation in a nonsmoking diabetic?*

DR GOLDSTONE: I really can't answer that definitively, but I think that your impression is correct. We rarely see patients with that degree of ischemia who are not smokers. Almost everybody we see in our practice smokes, and other studies have reported an incidence of smoking of 85% to 90% or higher.

PHYSICIAN IN THE AUDIENCE: *Regarding the EMED system analysis, what does the procedure cost, and how does it add to the whole program that you have described? When should it be ordered? How does it change the management of the diabetic foot or the use of regular podiatric care?*

DR STESS: The EMED is a new instrument. It has only been on the market since 1981 and is currently in operation at only a few medical centers. I think there are about 15 to 20 in the United States that have it, mostly research laboratories. The fee for a comprehensive analysis is $250. The first studies we did were reproducibility studies to make certain that the data were correct and to determine the number of times that we would have to walk a patient on the instrument to get a representative footstep. Each footstep is different, so we walk each patient five times and then derive a mean value to obtain a representative step.

The EMED is influencing our management in a key manner. First, just from a readout we can determine something not previously available—abnormal foot pressure distribution that occurs dynamically. There were previously a great many misconceptions about foot function: where a patient was loading a foot and what the pressure-time integrals were on a particular area. The data that we can now obtain allow us to construct orthotic devices that alleviate high pressure areas. We are also able to determine whether or not a surgical procedure is indicated. Although from an x-ray film bone abnormalities can be seen that result in high pressure, we had no idea before that a footstep takes anywhere from 0.6 to 1.2 seconds. Now we can identify with this instrument the amount of time spent on a particular area of the foot and design treatment, either orthotic devices, custom shoes, or surgery, consistent with the correction of those high pressures and to prevent a breakdown of skin due to pressure trauma.

PHYSICIAN IN THE AUDIENCE: *What is written on a foot prescription for footwear? How much are the charges? Does Medi-Cal or Medicare pay for them?*

DR STESS: There is a demonstration foot project that is being conducted right now by Medicare. If a patient has a history of foot ulceration or if a custom shoe is needed for a patient with diabetes, the project involves submitting a request to Medicare for approval for a custom shoe. Medicare will then randomly assign the patient to a group getting custom shoes or to a control group. Medicare is interested in the therapeutic effect of the shoe and hopes to demonstrate benefits. The cost of a custom shoe in the private sector runs anywhere from $300 to $1,500, depending on the type of deformity. Medicare will pay $300 to $350 for either a custom shoe or what they call an extradepth shoe with a custom insole.

PHYSICIAN IN THE AUDIENCE: *What do you write on the prescription?*

DR STESS: You may request a custom-molded shoe with ac-

commodation or an extradepth shoe with custom insole. Most of the pedorthists (prescription orthopedic shoe makers) have a good idea what is needed. What we do is provide the EMED footprint, isolating a particular area, and request accommodation with certain types of materials.

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